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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/621,725	03/21/96	LEHMANN	P CASE-02138

EXAMINER

18M1/0117

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ART UNIT	PAPER NUMBER
SCHWADRON, R	
1816	6

DATE MAILED: 01/17/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on 11/20/96

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) MB 1-9 is/are pending in the application.
Of the above, claim(s) 4-8 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-3, 9 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

[illegible] (Rev. 9/95)

15. Applicant's election without traverse of Group I and the species myelin basic protein in Paper No. 5 is acknowledged.

16. Claims 4-8,10-17 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions or species. Election was made **without** traverse in Paper No. 5.

17. Claims 1-3,9 are under consideration. Claims 11-17 have been cancelled.

18. Claims 1-3,9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not disclose how to use the method of the instant invention for the treatment of autoimmune disease in vivo in humans. The method of the instant invention reads on a method for the treatment of human disease in vivo. Applicant has not enabled the breadth of the claimed invention in view of the teachings of the specification because the use for the instant invention disclosed in the specification is the in vivo treatment of disease in humans. The state of the art is such that is unpredictable from the mouse data disclosed in the specification as to how the instant invention could be used for the treatment of disease in vivo in humans. The specification provides no working examples indicating that the method of the instant invention can be used for the treatment of human disease. Regarding the in vivo EAE mouse data disclosed in the specification. Osband et al. teaches that there exists a lack of useful animal models that can be applied to immunotherapy. Osband et al. further teach that animal models are not generally predictive of therapeutic efficacy in humans as relates to immunotherapy regimens. (see page 193 in particular). Furthermore, EAE is not a naturally occurring disease, it is created by injecting certain strains of mice with xenogeneic MBP.

The use of any particular pharmaceutical therapy for the treatment of human disease is unpredictable in the absence of appropriate evidence demonstrating that said therapy can be used for the treatment of disease for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an

inherently short half-life of the protein; (2) the protein may not reach the target area because, i.e. the protein may not be able to cross the mucosa or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment. It appears that undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification alone. See Ex parte Forman, 230 USPQ 546, BPAI, 1986.

19. Claims 1-3,9 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "Th2 Response Inducing Adjuvant" because it is unclear what this means or encompasses. While the specification discloses a particular Th2 Response Inducing Adjuvant (eg. IFA), there is no disclosure as to what other compounds are encompassed by this term. There is no disclosure in the specification as to what other compounds are encompassed by the term "Th2 Response Inducing Adjuvant" or guidance as to how the identity of said compounds would be elucidated. Therefore, the specification is not enabling for the instant invention.

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 1-3,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Namikawa et al. in view of prior art disclosed in the specification. The claims are drawn to methods of treating an autoimmune disease. Namikawa et al. teach that immunization with MBP in IFA (a Th2 Response Inducing Adjuvant as defined in specification) prevents EAE in rats (see page 932, first column, first paragraph). The specification discloses that the art recognizes certain

similarities between EAE and human MS (see page 2, first paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed method because Namikawa et al. teach that immunization with MBP in IFA prevents EAE in rats and the art recognized similarities between EAE and human MS. Namikawa et al. teach that after immunization, the response of cells to a T cell mitogen is tested (see Table 3 and page 934, column 1). The response of T cells would have been alternatively measured using art known lymphokine assays, because the art recognizes that activated T cells produce lymphokines in response to antigen. ELISA assays are known in the art as is the membrane recited in claim 2 (see specification, page 8, first paragraph).

22. No claim is allowed.

23. Papers related to this application may be submitted to Group 180 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 180 at (703) 305-7939.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Tuesday through Friday from 8:30 to 6:00. The examiner can also be reached on alternative Mondays. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1816
January 16, 1997